

Application No.: 10/623,193
Filing Date: July 18, 2003

REMARKS

In response to the Final Office Action mailed October 30, 2008, the Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following remarks.

Summary of the Office Action

In the October 30, 2008, Office Action, Claims 18, 23, 33-41, 43-44, 46, 50-59 and 61-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,527,312, issued to Ray (hereinafter "Ray"), in view of U.S. Patent No. 5,989,255, issued to Pepper et al. (hereinafter "Pepper"). In addition, Claims 45, 47-49 and 60 stand objected to by the Examiner as allowable but dependent from a rejected base claim. Claims 18, 23, 26, 33-41 and 43 were also rejected under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement.

Summary of the Amendment

Applicant has amended independent Claim 18 and dependent Claims 37, 45 and 60. Please note that in the amendments to the claims, deletions are indicated by strikethrough (e.g. ~~deletion~~) or double brackets (e.g. [[word]]) and additions to the claims are underlined (e.g. addition). Claims 24-25 have been canceled without prejudice. Claim 27 was previously withdrawn. Accordingly, Claims 18, 23, 26, 33-41 and 43-72 are currently pending and under examination in the present application. Applicant respectfully submits that the present application is in condition for allowance.

Independent Claim 18

In the Office Action, independent Claim 18 and various of its dependent claims stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ray in view of Pepper. While Applicant reserves the right to prosecute these claims as originally filed, Applicant has amended Claim 18 along the lines discussed during the interview in order to expedite prosecution of this Application. Specifically, Claim 18 now recites, in part, "to position a distal tip of the bone anchor within a pedicle of a second vertebra" and "mechanically decoupling the second portion from the first portion." Accordingly, Applicant respectfully requests that the rejection of Claims 18, as well as the claims dependent there from be withdrawn and that these claims be indicated as allowable over the art of record.

As discussed during the interview, support for extending the fixation device through the facet of a first vertebrae and into a pedicle of a second inferior vertebrae can be found in Figure 20 and paragraph 0113 of U.S. 2004/0127906 (publication of the present application).

Claims 18, 23, 26, 33-41 and 43 were also rejected under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement. To advance prosecution, Applicant has removed "native" from these claims.

Independent Claims 44 and 59

With respect to Independent Claims 44 and 59, Applicant respectfully traverses the rejection of these claims over the combination of Ray and Pepper. As noted in the previous response and discussed during the personal interview, the claimed inventions of Claims 44 and 59 are fundamentally distinct from the disclosure in Ray. Applicant's bone anchor enters the bone at a different point than does Ray, and resides at a different angle of inclination than that disclosed in Ray. Moreover, while Applicant's apply compression along Applicant's longitudinal axis of implantation, Ray is concerned about minimizing lateral movement, transverse to the longitudinal axis of the Ray implant.

With respect to the insertion angle, Ray discloses that conventional translaminal screw fixation may not be adequate to stabilize successive vertebra in those patients having first received a laminectomy. *See, e.g.*, column 1 lines 37 through 41:

When a laminectomy is required, the spinous process and the underlying lamina are removed. When the spinous process is removed, translaminal screw fixation is not generally adequate to stabilize successive vertebra pending healing of the spinal fusion.

Thus, referring to Figures 1, 2 and 3 in Ray, a laminectomy has been performed. Because Ray believes "translaminal screw fixation is not generally adequate" in these situations, Ray discloses a distinct and different approach from translaminal screw fixation in which the screw 20 is inserted "through the lamina 22" (column 2 line 37) and "angles laterally outwardly **into the left base of the transverse process 24 of the inferior vertebra.**" Column 2 lines 39

through 41 (emphasis added). “The screws 20 and 30 diverge in the anterior direction, and are also angled slightly in the inferior direction”. Column 2 lines 47 through 49.

The Final Office Action states at page 4 that “Ray requires at least a portion of the bone anchor to be situated within the pedicle of a vertebrae.” Applicant respectfully disagrees. As discussed during the interview, the conventional screw utilized by Ray enters the lamina in a patient following laminectomy, and extends laterally into the transverse process. In contrast, Applicant’s bone anchor enters the facet on a superior vertebral body and extends into the pedicle.

Nor is there any reason why one would seek to apply axial compression along the axis of the screw disclosed in Ray. Ray’s concern is with transverse motion of the screw, as a consequence of weakened bone due to the laminectomy. That is why Ray discloses the use of fixation bars 26 and 36, to minimize lateral movement of the screws 20 and 30. The fixation bars form a hook that extends over and around the adjacent pedicle to secure the bar from movement in an inferior direction. Column 3 lines 3 through 6. This arrangement resists lateral “togging” of the bone screw, as can be appreciated by reference to Figure 1 in Ray.

Nor does Pepper suggest modifying Ray in a manner that would produce the claimed invention. Although Pepper does disclose an orthopedic device which is capable of applying axial compression, there is no reason of record why a person of skill in the art would combine the teachings of Pepper and Ray to produce Applicant’s claimed invention.

For example, nothing in Pepper would suggest changing the angular orientation of the screws disclosed in Ray, away from the lamina to transverse process axis as disclosed in Ray and instead toward the presently claimed native facet to pedicle axis of Applicant’s present invention.

At most, the combination of the teachings of Pepper and Ray would likely produce a method as disclosed in Ray, in which the Pepper compression screw is introduced into the lamina of a laminectomy patient and extends into the transverse process as disclosed in Ray, and is provided with an anti-toggle bar. This fails to disclose or suggest Applicant’s claimed invention.

Independent Claims 44 and 59 both recite that the fixation device is advanced “through a facet of a first vertebra and into a pedicle of a second vertebra”. Accordingly, Applicant respectfully submits that these claims are allowable for at least the reasons discussed above.

Application No.: 10/623,193
Filing Date: July 18, 2003

Dependent Claims 45 through 58 depend ultimately from independent Claim 44, and Claims 61-72 depend on Claim 59 and are believed to be allowable at least for the reasons set forth above.

Declaration

As discussed during the interview, in support of the arguments submitted above, Applicant will be submitting with a supplemental amendment a declaration in support of the above arguments.

Claims 45 and 60

Applicant notes with appreciation that the Examiner has indicated that Claims 45 and 60 would be in condition for allowance if rewritten into independent form. According, Applicant has amended Claims 45 and 60 into independent form and submit that these claims are in condition for allowance. Claims 47-49 are also in condition for allowance because they depend upon Claim 45.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/199,516	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	8/8/2005
11/444,103	LOCKING PLATE FOR BONE ANCHORS	5/31/2006

Application No.: 10/623,193
Filing Date: July 18, 2003

Serial Number	Title	Filed
11/623,270	METHOD AND APPARATUS FOR SPINAL FIXATION	1/15/2007
11/099,431	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	4/5/2005
11/623,290	METHOD AND APPARATUS FOR SPINAL FIXATION	1/15/2007
11/099,431	PROXIMAL ANCHORS FOR BONE FIXATION SYSTEM	4/5/2005
11/036,781	GUIDANCE SYSTEM FOR SPINAL STABILIZATION	1/14/2005
11/056,991	METHOD AND APPARATUS FOR SPINAL STABILIZATION	07/20/2005
11/296,881	METHOD AND APPARATUS FOR SPINAL STABILIZATION	12/08/2005
11/050,975	METHOD AND APPARATUS FOR SPINAL FUSION	2/4/2005
10/830,631	METHOD AND APPARATUS FOR BONE FIXATION WITH SECONDARY COMPRESSION	4/23/2004
12/134,886	METHOD AND APPARATUS FOR SPINAL STABILIZATION	6/06/2008

CONCLUSION

Applicant respectfully submits that the above rejections and objections have been overcome and that the present application is now in condition for allowance. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claim and drawings in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the Applicant's attorney in order to resolve such issue promptly.

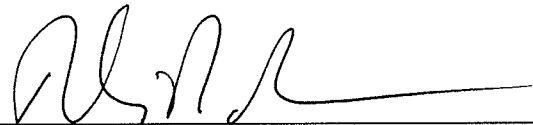
Application No.: 10/623,193
Filing Date: July 18, 2003

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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